Letter from the Deputy Associate Director for Science, CDC

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Local IRB Review of Severe Acute Respiratory Syndrome (SARS) Laboratory Investigational Test Protocols--CDC Protocols 3911 and 3918

Dean Erdman, Dr.P.H.
Principal Investigator, CDC Protocol 3911
Lia Haynes, Ph.D.
Principal Investigaor, CDC Protocol 3918
National Center for Infectious Diseases, CDC

This is to clarify issues concerning local institutional review board (IRB) review of Severe Acute Respiratory Syndrome (SARS) Laboratory Investigational Test Protocols from the Centers for Disease Control and Prevention: CDC Protocol 3911-- Implementation of the SARS coronavirus real-time RT-PCR assay at participating public health laboratories to detect SARS-CoV in respiratory secretions, blood, plasma, serum and stool; and CDC Protocol 3918--Implementation of the SARS coronavirus EIA assay at participating public health laboratories to detect SARS-CoV in blood samples.

The scope of possible use of these protocols cannot be definitively determined at this time. In addition, the need to have these protocols widely available at this time as well as the possible urgent nature of utilizing these tests for a public health response to a SARS epidemic makes local IRB review problematic. Accordingly, CDC has elected to use the CDC IRB as a national IRB to review these protocols, and the Food and Drug Administration has concurred in this decision. Unless otherwise precluded by local law or institutional policy, each local site that becomes involved in these protocols may rely on the CDC IRB to meet the FDA regulatory requirements of IRB review. Instructions to this effect will be included in the materials distributed to participating sites.

Sites which are precluded by local law or institutional policy from relying on another IRB, or those sites that otherwise decide to perform their own IRB review regardless of the national IRB review, need to consider the following factors in their review.

- CDC has determined that the use of these investigational tests for use in detecting SARS-CoV infection does not constitute research subject to regulation under 45 CFR 46.102(d). Therefore, these protocols should be reviewed for compliance with FDA regulations found at 21 CFR 50 and 56.

- FDA has determined that protocol 3918 does not require an Investigational Device Exemption as outlined in 21 CFR 812.2(b).

- Due to time constraints and competing priorities, CDC program and IRB staff will not be able to respond to specific issues and concerns arising from these reviews. If substantial issues are identified which prevent approval, the local site may be referred to FDA for guidance on use of these products.

- FDA regulations concerning one-time emergency use of investigational products prior to IRB review may be applicable in certain settings. Consult with your local human research protection program for guidance and procedures.

I hope that this clarifies the issues concerning local IRB review of these protocols.

John R. Livengood, M.D., M.Phil.

For more information, visit www.cdc.gov/ncidod/sars or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)